TAB 5

Tissue Related Documents

Compliance Program

FDA Form 3356 - Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue Based-Products (HCT/Ps)

Human Cell Products

Human Cell and Tissue Device Products

Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P) - Registered Establishments

Reproductive Cells and Tissue

- Assisted Reproductive Technology - Center for Disease Control and Prevention (CDC)

Xenotransplantation Products

Guidances and Rules

FEDERAL REGISTER Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule - **5/25/2004** - *(PDF)*, *(Text)*

- Questions and Answers for Roll-Out of Donor Eligibility Final Rule and Draft Guidance - *(Text)*
- FDA Finalizes New Rule on Donor Eligibility for Human Tissues and Cells - **5/20/2004**

Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - **5/20/2004** - *(PDF)*, *(Text)*

- FEDERAL REGISTER Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability - **Comments by August 23, 2004** (Text)

FEDERAL REGISTER Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Interim Final Rule; Correction - **1/30/2004** - *(PDF)*, *(Text)*

- FEDERAL REGISTER Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Interim Final Rule; Opportunity for Public Comment - **1/23/2004** - *(PDF)*, *(Text)*

- FEDERAL REGISTER Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Final rule; delay of effective date - **1/21/2003** - *(PDF)*, *(Text)*

- FEDERAL REGISTER Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Final Rule - **1/19/2001**- *(PDF)*, *(Text)*

    - Q and A's Concerning Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Draft Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs) - **8/15/2003** - *(PDF)*, *(Text)*

Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)- **6/14/2002** - *(PDF)*, *(Text)*

FEDERAL REGISTER Combination Products Containing Live Cellular Components; Public Hearing - **5/15/2002** *(PDF)*, *(Text)*

Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation - **3/8/2002** - *(PDF)*, *(Text)*

Human Cells or Tissues Intended for Transplant Into a Human Recipient That Have Ex-vivo Contact With Live Nonhuman Animal Cells, Tissues, or Organs Letter - **3/8/2002** - *(PDF)*, *(Text)*

Information and Recommendations for Physicians Involved in the Co-Culture of Human Embryos with NonHuman Animal Cells

Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts - **2/1/2002** - *(PDF)*, *(Text)*

Letter to National Governors Association on " Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement - **1/19/2001** - *(PDF)*, *(Text)*

FEDERAL REGISTER Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed Rule - **1/8/2001** - *(PDF)*, *(Text)*

FDA Proposes New Rules for "Good Tissue Practice" - **1/5/2001**

Office of Inspector General - January 2001 Report: Informed Consent in Tissue Donation, Expectations and Realities - (PDF)

Office of Inspector General - January 2001 Report: Oversight of Tissue Banking - - *(PDF)*

Human Bone Allograft: Manipulation and Homologous USe in Spine and Other Orthopedic Reconstruction and Repair; Public Meeting: Reopening of Comment Period - **12/13/2000** - *(PDF)*, *(Text)*

Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens - **6/23/2000** - *(PDF)*, *(Text)*

Guidance for Industry - Screening and Testing of Donors of Human Tissue Intended for Transplantation - **7/29/1997** - *(PDF)*, *(Text)*

FEDERAL REGISTER Human Tissue Intended for Transplantation; Final Rule - **7/29/1997** - *(PDF)*, *(Text)*

Proposed Approach to Regulation of Cellular and Tissue-Based Products - **2/28/1997** - *(PDF)*, *(Text)*

Reinventing the Regulation of Human Tissue - **2/1997**
- Tables - *(PDF)*

FEDERAL REGISTER Notice Public Hearing: Products Comprised of Living Autologous Cells Manipulated ex vivo and Intended for Implantation for Structural Repair or Reconstruction - **7/18/1995** - *(PDF)*, *(Text)*

FEDERAL REGISTER Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice - **10/14/1993** - *(PDF)*

Tissue Action Plan

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